DSJ1&2-PR Exh 546

Subject: FW: SOM Intro Call - 4:00pm Eastern Time
Location: Please call 888-287-4068 and code 734128

Start: Mon 12/1/2008 9:00 PM
End: Mon 12/1/2008 9:45 PM

Recurrence: (none)

Meeting Status: Accepted

Organizer: GLOTZ Gary

Is there anyone else who would need to sit in on this initial call?

-----Original Appointment-----
From: GLOTZ Gary
Sent: Monday, December 01, 2008 11:54 AM
To: GLOTZ Gary; LeeAnn Smith; HAMBY Paul
Subject: SOM Intro Call - 4:00pm Eastern Time
When: Monday, December 01, 2008 3:00 PM-3:45 PM (GMT-06:00) Central Time (US & Canada).
Where: Please call 888-287-4068 and code 734128

<<SOM Introduction_ Qualitest.ppt>>
Please find the attached SOM presentation. We are confirmed for 4:00pm EST today. Please call 888-287-4068 and code 734128.

Gary

From: LeeAnn Smith [mailto:lsmith@qualitestrx.com]
Sent: Monday, December 01, 2008 12:23 PM
To: GLOTZ Gary
Subject: RE: Compliance Solutions Demo request

We'll take the 4:00 time slot. Joining in from my side will be Spike Pannell and John Schultz, plus myself. Will you contact us, or will you provide a call in number?

Thank you for your time.
LeeAnn Smith
Information Technology
ole1.bmp
character. commitment. community.
Qualitest/Vintage Pharmaceuticals
120, 130, 150 Vintage Drive
Huntsville, AL 35811, USA
Tel: +1 256-859-4011 x3029
Cell: +1 256-759-7475
lsmith@qualitestrx.com
From: GLOTZ Gary [mailto:Gary.Glotz@dendrite.com]
Sent: Monday, December 01, 2008 10:22 AM

To: LeeAnn Smith
Subject: RE: Compliance Solutions Demo request

Hello LeeAnn.

We have either 2:30pm or 4:00pm EST open today. Once you confirm, I will send you a meeting invite and an intro PPT on SOMs.

Thanks

Gary Glotz | Sales Director, Regulatory Compliance
Cegedim Dendrite | 1025 Boulders Parkway, Suite 405, Richmond, VA, 23225
Tel: 888-590-9954 x5003 | Fax: 804-267-1746 | Cell: 804-677-6465 | email: gary.glotz@dendrite.com
ole2.bmp

ole3.bmp

From: LeeAnn Smith [mailto:lsmith@qualitestrx.com]
Sent: Monday, December 01, 2008 10:17 AM
To: GLOTZ Gary
Subject: RE: Compliance Solutions Demo request

Yes – this week would be wonderful… Might you have time this afternoon!

LeeAnn Smith
Information Technology
ole4.bmp
character. commitment. community.
Qualitest/Vintage Pharmaceuticals
120, 130, 150 Vintage Drive
Huntsville, AL 35811, USA
Tel: +1 256-859-4011 x3029
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lsmith@qualitestrx.com
From: GLOTZ Gary [mailto:Gary.Glotz@dendrite.com]
Sent: Monday, December 01, 2008 8:53 AM
To: LeeAnn Smith
Subject: RE: Compliance Solutions Demo request

Hello LeeAnn,

Can we setup a call this week to discuss SOMs? I tried to call you but you phone was off.

Thank you,

Gary

Gary Glotz | Sales Director, Regulatory Compliance
Cegedim Dendrite | 1025 Boulders Parkway, Suite 405, Richmond, VA, 23225
Tel: 888-590-9954 x5003 | Fax: 804-267-1746 | Cell: 804-677-6465 | email: gary.glotz@dendrite.com
ole5.bmp

ole6.bmp

From: GLOTZ Gary
Sent: Monday, November 24, 2008 3:33 PM

To: lsmith@qualitestrx.com
Subject: FW: Compliance Solutions Demo request

Hello LeeAnn,

I received your email regarding wanting a discussion regarding putting a compliance SOM program in place.

Is your team available at 11:30am EST on Dec 1?

Thank You,

Gary

Gary Glotz | Sales Director, Regulatory Compliance
Cegedim Dendrite | 1025 Boulders Parkway, Suite 405, Richmond, VA, 23225
Tel: 888-590-9954 x5003 | Fax: 804-267-1746 | Cell: 804-677-6465 | email: gary.glotz@dendrite.com
ole7.bmp

ole8.bmp

From: SUPPORT Sales
Sent: Monday, November 24, 2008 2:30 PM
To: Marketing Leads
Subject: schedule-www.dendrite.com/DEASolutions?ID=421

First Name: LeeAnn
Last Name: Smith
Company: Qualitest Pharmaceuticals
Email: lsmith@qualitestrx.com
Phone: 256-859-4011
Title: IT Director
Origin: North America
Schedule Date: Dec--1-2008 Morning
Comment: In the process of reviewing our current suspicous order monitoring process, but we are well aware that what we have is NOT compliant by today's standards. We are looking for assistance....

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Compliance Solutions ***Powered by BuzzeoPDMA***

Suspicious Order Monitoring

Paul Hamby, Director, Consulting and Validation

Gary Glotz, Sales Director – Compliance Solutions

cegedim dendrite

Regulatory Compliance Solutions

Division Overview

- Founded in 1991 (formerly BuzzeoPDMA)
- Acquired by Dendrite International in January 2005, then Cegedim acquired Dendrite in May of 2007.
- 120+ Employees in Compliance Solutions – Richmond & NJ Offices
- Areas of Focus
  - **Controlled Substances Act and DEA Policy**
  - **Prescription Drug Marketing Act and FDA Policy**
  - **State Specific Regulatory Requirements**
  - **Computer System Validation and Part II consulting**
  - **Operational Support via Outsourcing**
- 250+ Clients, including small, medium and large pharmaceutical companies, drug wholesalers and pharmacy retailers
- Regulatory and Operational Experience-based
- Professional Working Relationships with DEA, FDA, State Agencies, and Regulatory Law Firms

Compliance Trends

DEA, US Attorneys, and State agencies are increasing scrutiny in all areas, particularly in Manufacturing, Distribution, R & D, and Pharmacy related to controlled drugs and listed chemicals

- Companies are not meeting the regulatory requirements
- Inconsistent implementation and lack of understanding of regulatory requirements
- Increase in inspections by DEA, states

- **Multi-Million dollar fines and penalties being levied**
- **Several large pending cases**
  - Pharmacy
  - Manufacturer
  - Distributor

Supply Chain Impact

- A number of companies have had actions taken against them by DEA for having non-complaint SOM programs
- SOM, as well as appropriate due diligence and “know your customer” efforts, are key to DEA’s efforts to curb diversion of controlled drugs and listed chemicals
- DEA Actions:
  - Immediate Suspension of DEA Registrations
  - Show Cause actions to deny the DEA Registration
  - Loss of DEA Registration
  - Large Civil Fines
  - Subpoenas / Criminal prosecution

SOM Requirements

Controlled Substances – Requirement 21CFR 1301.74 (b)

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

- **Further iterated in September 06, February 07, and December 2007 DEA letters**

Listed Chemicals – Requirements under 21 CFR 1309.71

(a) *All applicants and registrants must provide effective controls and procedures to guard against theft and diversion of List 1 chemicals…*

(b) *In evaluating the effectiveness of security controls and procedures, the Administrator shall consider the following factors:*

…

(8) The adequacy of the registrant's or applicant's systems for monitoring the receipt, distribution, and disposition of List 1 chemicals in its operations.

- **In addition, DEA's Chemical Handler's Manual devotes several pages to know-your-customer and proof of identity/due diligence issues.**

Challenges of SOM

- **Many organizations have operated using the old "excessive purchase report" approach**
  - After the fact, monthly listing of "excessive purchases" to DEA
- **Those organizations that are looking at SOM, frequently establish quantity based threshold systems to flag potentially suspicious orders if they exceed a certain buying volume.**

  Many of these thresholds are:
  - Arbitrarily set values based on a "best guess" of reasonable values at which to flag or pend orders
  - Not statistically supportable
- **Arbitrarily set values do not satisfy the regs and do not typically anticipate the dynamics associated with evaluating order pattern, frequency, size of orders, size and categories of accounts, etc.**
  - Reference the December 2007 DEA letter
- **What practices should be followed once an account is "flagged" as potentially suspicious?**

SOM Recommendations

- **Develop a "total SOM solution" to review each of your customer's orders product by product, comparing orders with historical ordering patterns for that customer and product.**
- **Determine the legitimacy of EVERY order BEFORE IT IS SHIPPED.**
- **Include all controlled substances (Schedule II, III, IV, and V) and listed chemicals.**
- **Actions:**
  - Update order management system to include a statistically based model to identify suspicious orders
  - Complete a formal computer system validation to confirm the accuracy and suitability of the system
  - Institute best practices for investigation and disposition of accounts flagged as potentially suspicious
- **Overall Objective: A total SOM program that meet DEA requirements**
  - Statistically viable system (justifiable & defensible)
  - Statistics, methodologies, and indexes are confirmed and validated
  - Potentially suspicious accounts are investigated so informed decisions can be made on continuing service to the account

Statistically Defensible Order Pending System

- Rather than looking just at purchasing volume, evaluates a variety of order characteristics (such as order size, history, trends, frequency, etc.)
- Based on and grounded in statistics, not "best guesses"
- A good model will automatically "retune" itself as a customer's ordering pattern changes over time

Computer Systems Validation

- **Software testing – confirms the updated, statistically based system:**
  - functions properly
  - establishes appropriate values and levels where orders are pended, and
  - pends (or holds) orders consistent with DEA requirements
- **Results in a set of fully executed testing procedures and summary documentation – "Documented evidence" that the statistically based system functions consistent with regulatory requirements**

Account Investigation and Disposition

- **Establish appropriate practices for investigation of potentially suspicious accounts**
  - SOPs on “rules” around account investigation and order release
  - Scripts for support team members to use with personnel from accounts under evaluation
  - Customer self assessment questionnaires
  - On-site account verification visits
  - Compliance certification forms
  - New account investigation
  - Etc.

- **In all cases, the focus should be on developing an Account Investigation and Disposition program that will identify and suspend orders received from potentially illicit operations, but clear legitimate orders for quick shipment.**

Q&A

- Q&A?

- Contact Info:

Paul Hamby paul.hamby@dendrite.com;
678-474-8559

Gary Glotz gary.glotz@dendrite.com